JUL 13 2012

9. 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K121745

Applicant Information:

Date Prepared:	June 13, 2012
Name:	BridgePoint Medical
Address:	13355 10th Ave. N., #110 Plymouth, MN 55441 Phone: 763-225-8500 Fax: 763-225-8718
Contact Person:	Jill Munsinger
Phone Number:	office: 763-225-8510 / cell: 651-270-0572
E-mail:	jmunsinger@bridgepointmedical.com

Device Information:

Classification:	Class II Percutaneous Guidewire
Trade Name:	Mantaray™ Guidewire
Common Name:	Percutaneous Guidewire
Classification Name:	Percutaneous Guidewire

Predicate Devices:

The additional models and modified BridgePoint Medical Mantaray™ Guidewires are substantially equivalent in intended use, method of operation and technical aspects to the following predicate device:

K120881 – Mantaray™ Guidewires
K120533 – BridgePoint Medical Peripheral System

Device Description:

The additional models and modified Mantaray™ Guidewires are conventionally constructed, single use, disposable guidewires that consist of a full-length stainless steel shaft with proximal PTFE coating where the distal portion of the stainless steel core is taper ground to provide distal flexibility. The distal portion also includes a coaxially positioned coil constructed of platinum/tungsten material for visibility under fluoroscopy. The coil is fixed to the stainless steel core wire via silver alloy solder and is coated with hydrophilic coating. The distal tip of the guidewire is supplied with an angled geometry which transitions to a conventional rounded tip. A short extension with an approximate diameter of 0.0035"-0.0065" (which is a monolithic extension of the core wire) extends approximately 0.007" distal of the rounded tip.

Intended Use:

The BridgePoint Medical Mantaray™ Guidewires when used as part of the BridgePoint Medical Peripheral system are intended to facilitate placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

Comparison to Predicate Device(s):

The additional models and modified Mantaray™ Guidewires are substantially equivalent to the previously cleared Mantaray™ Guidewires that are utilized in the BridgePoint Medical Peripheral System, K120533, in that they are all designed to facilitate placement of conventional guidewires beyond stenotic peripheral lesions prior to placement of other interventional devices.

The additional models of Mantaray™ Guidewires are a result of modifications to the overall guidewire length as compared to previously cleared models. The additional models of Mantaray™ Guidewires and previously cleared Mantaray™ Guidewires are manufactured using the same general processes and components and have the same physical attributes (flexibility, radiopacity, lubricity, tensile, torque, etc.). The distal tips of each device are radiopaque and can be seen with fluoroscopy for precise placement. All devices are highly lubricious for smooth delivery of multiple devices.

The modifications made to the originally cleared Mantaray™ Guidewires include a modification in the core wire material and colorant compound used in the proximal PTFE coating. The core wire material is being modified from 304 stainless steel to 302 stainless steel. The PTFE colorant is being modified from chromium oxide green (CAS 1308-38-9) to cobalt titanate green (CAS 68186-85-6). Both of the new materials (core wire and proximal coating colorant) are currently used on other legally marketed devices within the same classification regulation for the same intended use.

Performance Data:
The additional models and modified Mantaray™ Guidewires have been evaluated using the following *in vitro* bench testing to confirm the performance characteristics as compared to the predicate device:

- Tensile
- Dimensional
- Guidewire Insert & Withdrawal
- Flexibility
- Fatigue
- Coating
- Torque
- Surface Defects
- Corrosion
- Tip Memory, and
- Radiopacity

In vivo testing was not deemed necessary based on the significance of the proposed modifications to the baseline device. The shorter length guidewires and modified proximal coating formulation results in a device that meets the original design requirements of the currently marketed Mantaray™ Guidewires as demonstrated in the bench tests above. Animal studies were successfully completed with the currently marketed Mantaray™ Guidewires.

Biocompatibility tests were completed to ensure all materials utilized to construct the modified Mantaray™ Guidewires were biocompatible. Biocompatibility tests included:

- Cytotoxicity
- Kligman Sensitization
- Irritation
- Acute Systemic Cytotoxicity
- Pyrogen
- Hemocompatibility (Direct & Indirect)
- *In Vitro* Hemocompatibility
- Complement Activation Assay (Indirect)
- *In Vivo* Thrombogenicity, and
- Unactivated Partial Thromboplastin Time.

All test results demonstrated the materials, manufacturing processes, and design of the modified Mantaray™ Guidewires met the established performance criteria and will perform as intended.

Summary:

Based upon the intended use and descriptive information provided in this pre-market notification, the additional models and modifications to the BridgePoint Mantaray™ Guidewires have been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BridgePoint Medical, Inc.
c/o Jill Munsinger
13355 10th Ave N, Ste. 110
Plymouth, MN 55441

JUL 13 2012

Re: K121745
Trade/Device Name: BridgePoint Medical Peripheral System: Mantaray™ Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 13, 2012
Received: June 14, 2012

Dear Ms. Munsinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

8. INDICATIONS FOR USE STATEMENT

510(k) Number: (TBA) ~~K121745~~ K121745

Device Name: **BridgePoint Medical Peripheral System**

Indications For Use:

The BridgePoint Medical Peripheral System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121745